K000590

MAY 11 2000

510(k) Summary of Safety and Effectiveness

(1)

Submitter's name:	Encore Orthopedics, Inc.
Submitter's address:	9800 Metric Blvd, Austin, TX 78758
Submitter's telephone number:	(512) 834-6237
Contact person:	Debbie De Los Santos
Date summary prepared:	February 14, 2000

(2)

Trade or proprietary device name:	Lateral Pivot Insert
Common or usual name:	Tibial Insert
Classification name:	Class II

(3) **Legally marketed predicate device:** Foundation Primary Insert and Ultra Congruent Insert (Encore Orthopedics, Inc.)

(4) **Subject device description:** This device is used in conjunction with the Foundation tibial baseplates and femurs and is utilized in treating patients who are candidates for cemented primary total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. The Lateral Pivot Insert is available in 7 sizes (2, 3, 4, 6, 8, 10, and 12) and 5 thicknesses (9, 11, 13, 15, and 19) and are provided in right and left configurations. The lateral side of the insert is similar to the Ultra-Congruent insert. The medial side of the insert is similar to the primary insert. This insert is intended to more closely match the kinematics of the knee, allowing some rotation along the medial condyle and increased congruency along the lateral condyle.

(5) **Subject device intended use:** This device is part of a total knee replacement system utilized in treating patients who are candidates for primary cemented total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function.

- Noninflammatory degenerative joint disease including osteoarthritis or traumatic arthritis
- Avascular necrosis of the femoral condyle
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy
- Moderate valgus, varus or flexion deformities
- Rheumatoid arthritis
- Treatment of fractures that are unmanageable using other techniques.

(6) **Basis for Substantial Equivalence:** Features comparable to predicate devices include same materials, design and indications as the Foundation Primary Knee System (K923277) and Ultra-Congruent Insert (K963028).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2000

Ms. Debbie De Los Santos
Regulatory/Clinical Specialist
Encore Orthopedics, Inc.
9800 Metric Boulevard
Austin, Texas 78758

Re: K000590
Trade Name: Lateral Pivot Insert
Regulatory Class: II
Product Code: JWH
Dated: February 14, 2000
Received: February 22, 2000

Dear Ms. De Los Santos:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Donna R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K000590

Device Name: Lateral Pivot Insert

Indications For Use:

Lateral Pivot Insert
Indications For Use

This device is part of a total knee replacement system utilized in treating patients who are candidates for primary cemented total knee arthroplasty or revision arthroplasty where bone loss is minimal and the collateral ligaments are intact. It is intended to aid the surgeon in relieving the patient of knee pain and restoring knee joint function.

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- Treatment of fractures that are unmanageable using other techniques.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Bachman

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000590

Prescription Use ✓ OR Over-The-Counter Use ____
(per 21 CFR 801.109)

(Optional Format 1-2-96)